

**Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)**

*The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box VIII (iv). If this Box is not used, this sheet should not be included in the request.*

**Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))  
for the purposes of the designation of the United States of America**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/US04/10007 (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international applications designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

**Prior Applications:**

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: BEN-MENACHEM, Gil

Residence: Rockville, Maryland  
(city and either US state, if applicable, or country)

Mailing Address: 1714 Mark Lane, Rockville, Maryland 20852, United States of America

Citizenship: Israel

Inventor's Signature: Gil Ben-Menachem  
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 5/20/2004  
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: KUBLER-KIELB, Joanna

Residence: Rockville, Maryland  
(city and either US state, if applicable, or country)

Mailing Address: 212 Congressional Lane #201, Rockville, Maryland 20852, United States of America

Citizenship: Poland

Inventor's Signature: Joanna Kielb  
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 05/20/04  
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

☒ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

**Continuation of Box No. VIII (i) to (v) DECLARATION**

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Name: SCHNEERSON, Rachel

Residence: ~~Bethesda, Maryland~~  
(city and either US state, if applicable, or country)

Mailing Address: 10601 Weymouth Street, Bethesda, Maryland 20814, United States of America

Citizenship: USInventor's Signature: R. Schneerson  
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)Date: 6.1.04  
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: ROBBINS, John B.

Residence: ~~Chevy Chase, Maryland~~  
(city and either US state, if applicable, or country)

Mailing Address: 3901 Rosemary Street, Chevy Chase, Maryland 20815, United States of America

Citizenship: USInventor's Signature: John B. Robbins  
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)Date: 6.1.04  
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: POZSGAY, Vince

Residence: ~~Rockville, Maryland~~ Washington, DC  
(city and either US state, if applicable, or country)Mailing Address: 1745 UPSHUR ST. NW, WASHINGTON, DC 20011  
~~5901 Montrose Road, Apt No. C1105, Rockville, Maryland 20852, United States of America~~Citizenship: USInventor's Signature: V. Pozsgay  
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)Date: 5/20/2004  
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Citizenship: **Israel**

Inventor's Signature: Gil Ben-Menachem  
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Residence: **Rockville, Maryland**  
(city and either US state, if applicable, or country)

Mailing Address: **212 Congressional Lane #201, Rockville, Maryland 20852, United States of America**

Citizenship: **Poland**

Inventor's Signature: Joanna Kubler-Kielb  
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~~Rockville, Maryland~~  
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Mailing Address: 1745 UPRUR ST. NW, WASHINGTON, DC 20011  
~~5901 Montrose Road, Apt No. C1105, Rockville, Maryland 20852~~, United States of America

Citizenship: US

Inventor's Signature: V. Pozsgay  
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Citizenship:

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# PCT

## GENERAL POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

(PCT Rule 90.4)

The undersigned applicant:

**THE GOVERNMENT OF THE UNITED STATES OF AMERICA**, as represented by the Secretary, Department of Health and Human Services.

hereby appoints the following persons as :

☒ agent

☐ common representative

### Name and address

(Family name followed by given name; for a legal entity, full official designation. The address must include a postal code and name of country.)

Haight, James C.; Sadowski, David R.; Benson, Robert; Spiegel, Jack; Rucker, Susan S.; Finley, Stephen L.; Ferguson, Steven; Kim, John Peter; Pontzer, Norbert; Rodriguez, Richard U.; Shinn, Marlene; Berkley, Dale; and Joyce, Catherine M. all of the National Institutes of Health, Office of Technology Transfer, 6011 Executive Boulevard, Suite #325, Rockville, Maryland 20852, U.S.A., acting under authority of the Department of Health and Human Services, Government of the United States of America; and

Bunker, Gillian L.; Caldwell, Lisa M.; Carlson, Anne; Haendler, Jeffrey B.; Harding, Tanya M.; Jones, Michael D.; Maurer, Gregory L.; Mirho, Charles A.; Noonan, William D.; Polley, Richard J.; Rupert, Wayne W.; Rybak, Sheree L.; Siegel, Susan Alpert; Slater, Stacey C.; Stephens Jr., Donald L.; Stuart, John W.; Zastrow, Devon J. all of the firm of Klarquist Sparkman, LLP, Suite 1600, 121 S.W. Salmon Street, Portland, Oregon, 97204, U.S.A.

as agents to represent the undersigned before all the competent International Authorities in connection with all international applications filed by the undersigned with the United States Patent & Trademark Office as Receiving Office and to make or receive payments on behalf of the undersigned.

Address all correspondence to :

William D. Noonan, M.D.  
KLARQUIST SPARKMAN, LLP  
One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, OR 97204-2988  
(503) 226-7391  
(503) 228-9446 - Facsimile

The National Institutes of Health Office of Technology Transfer has been duly delegated responsibility for such patent matters under the authority of the Department of Health and Human Services Secretary Louis W. Sullivan's memorandum of May 21, 1991, appearing in the Friday June 7, 1991 Federal Register Notices at Volume 56, Number 100, pages 26418-26419. The undersigned is authorized to exercise such authority in this matter.

By:

James C. Haight

Reg No: 25,588

For: Mark Rohrbaugh, Acting Director

Office of Technology Transfer

National Institutes of Health

6011 Executive Blvd., Suite 325

Rockville, Maryland 20852 USA

Telephone: (301) 496-7056

Facsimile: (301) 402-0220

Date: FEB 2002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
National Institutes of Health

Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

February 2, 2004

Nicholas P. Godici  
Commissioner for Patents  
U.S. Patent and Trademark Office (USPTO)  
2121 Crystal Drive  
Crystal Plaza #2 – Suite 910  
Arlington, Virginia 22202

**Re: Delegation of Authority for Certain Patent Administration and Prosecution Activities**

Dear Sir:

Effective this date and acting under the authority set forth in DHHS Secretary Louis W. Sullivan's May 21, 1991 memorandum appearing in the Friday, June 7, 1991 Federal Register Notices at Volume 56, Number 110, pages 26418-26419 (copy attached), I authorize:

Astor, Marlene (Reg. No. 46,005);  
Berkley, Dale (Reg. No. 42,319);  
Ferguson, Steven (Reg. No. 38,448);  
Finley, Stephen (Reg. No. 36,357);  
Haight, James C. (Reg. No. 25,588);  
Joyce, Catherine M. (Reg. No. 40,668);  
Kim, John Peter (Reg. No. 38,514);  
Kindra, Jasbir (Reg. No. 41,115);  
Pontzer, Norbert (Reg. No. 40,777);  
Rodriguez, Richard U. (Reg. No. 45,980);  
Rucker, Susan S. (Reg. No. 35,762);  
Sadowski, David R. (Reg. No. 32,808);  
Schmickel, David (Reg. No. 40,270);  
Shmilovich, Michael A. (Reg. No. 45,634); and,  
Spiegel, Jack (Reg. No. 34,477)

to exercise full authority in United States or International patents or patent applications in which the Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, is an applicant or has an ownership interest with respect to the following:

- ☐ Signing original, associate, or substitute powers of attorney before the U.S. or International Authorities;
- ☐ Signing Request Forms, Demand Forms, and other documents filed in applications before the International Authorities;

Page 2: Delegation of Authority for Certain Patent Administration and Prosecution Activities

- ☐ Signing assignee's consent to changes in inventorship;
- ☐ Signing papers required from an assignee in connection with an application for Re-issue and/or Re-examination of a patent;
- ☐ Signing terminal disclaimers including, but not limited to, terminal disclaimers to obviate obviousness-type double patenting rejections; and,
- ☐ Signing all documents before the USPTO, either as the U.S. National Office or as a designated Receiving Office under the Patent Cooperation Treaty that can be signed by an assignee in patent matters.

Sincerely,



Mark L. Rohrbaugh, Ph.D., J.D.  
Director  
(Reg. No. 43,055)

Attachment

cc:  
James J. Groody (PTO)  
OTT Staff

Citation  
56 FR 26418-02  
1991 WL 300366 (F.R.)  
(Cite as: 56 FR 26418)

Found Document

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## NOTICES

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Office of the Secretary

## Office of the General Counsel; Statement of Organization, Functions and Delegations of Authority

Friday, June 7, 1991

\*26418 Part A, chapter AG (Office of the General Counsel, Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services. (38 FR 17033, June 20, 1973, as amended most recently in pertinent part at 55 FR 17500, April 25, 1990), and part H, chapter HN (National Institutes of Health, Public Health Service) (40 FR 22839, May 27, 1975, as amended most recently in pertinent part at 55 FR 35366, August 29, 1990), are amended to:

(1) Delete the Department Patent Officer (AG.35) and transfer patent administration and prosecution responsibilities from this Officer to the Office of Technology Transfer (HNA432), Office of Intramural Affairs (HNA43), Office of Intramural Research (HNA4), Office of the Director (HNA), National Institutes of Health (NIH), Public Health Service (H). Patent administration and prosecution activities will be consolidated with patent licensing functions within a single NIH organizational entity in order to improve program and resource management; and

(2) Retain patent legal services of the Department Patent Officer (AG.35) in the Public Health Division (AG.22.6), Office of the General Counsel, Office of the Secretary, and update the functional statement for the Public Health Division to reflect its responsibilities more accurately.

## Office of the Secretary

Under Chapter AG, Office of the General Counsel, Sections AG.35 (Department Patent Officer) and AG.22.6 (Public Health Division), delete the titles and statements in their entirety and substitute the following:

Public Health Division (AG.22.6). The Public Health Division shall provide legal services, including patent legal services, for programs administered by the Public Health Service (except the Food and Drug Administration), e.g., the Office of the Assistant Secretary for Health, and the agencies and offices of the Public Health Service (other than FDA), including the Office of Technology Transfer and the Patent Policy Board.

## Public Health Service



56 FR 26418-02  
(Cite as: 56 FR 26418, \*26418)

Under Chapter HN, National Institutes of Health, Section HNA, Office of the Director, Office of Intramural Affairs (HNA43), add the following title and statement:

Office of Technology Transfer (HNA432). (1) Develops policy and procedures for NIH, ADAMHA, and CDC to follow for the implementation of Cooperative Research and Development Agreements (CRADAs), patent licenses, and other technology transfers; (2) implements Patent Policy Board decisions and policies; (3) drafts, negotiates, and periodically revises model forms and agreements; (4) provides advice to ICDS on problem licenses and agreements; (5) develops policy statements on various technology transfer issues such as conflicts of interest; (6) tracks the OTT budget and prepares an annual status report to the NIH Office of the Director; (7) provides coordination and management of goals, functions, and operations of the Technology Management Branch, Technology Licensing Branch, and the Technology Transfer Coordination Branch; (8) coordinates and provides planning and liaison support for \*26419 international CRADAs and technology transfers; (9) creates and implements special programs relating to technology transfer by State and local governments and universities; (10) drafts and presents Congressional testimony, and drafts technology transfer-related responses to other Congressional inquiries; (11) provides operational management activities; (12) assists the Office of the General Counsel (OGC) in evaluating patent-related litigation matters; (13) in consultation with OGC and the involved agency component, as appropriate, negotiates settlements on contested matters with licensees or other parties involved with NIH, ADAMHA, and CDC in technology transfer or utilization matters; (14) represents the NIH, ADAMHA, and CDC in technology transfer or utilization matters; (15) represents the above agencies at a variety of professional conferences and other public fora; (16) investigates special issues; (17) evaluates the need for and develops new programs in technology management and technology transfer for the above agencies; (18) develops licensing strategies for NIH/ADAMHA/CDC intramural and CRADA inventions; (19) negotiates licenses and other technology transfers; (20) works with scientist inventors, contract attorneys and others in preparing patent applications and prosecuting these applications at the Patent Office level; (21) handles infringements in consultation with the OGC at the Patent Office level; and (22) makes recommendations to the OGC for referral of matters to the Department of Justice.

Dated: May 21, 1991.

Louis W. Sullivan,

Secretary.

[FR Doc. 91-13423 Filed 6-6-91; 8:45 am]

BILLING CODE 4150-04-M

56 FR 26418-02, 1991 WL 300166 (F.R.)  
END OF DOCUMENT